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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,488

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Jonathan Lightner

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,488	<b>Applicant(s)</b> LIGHTNER ET AL.	
	<b>Examiner</b> Elizabeth F. McElwain	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/31/06;4/9/07</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-8, in the reply filed on April 3, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9-11 are withdrawn, as drawn to a non-elected invention.

### ***Claim Objections***

Claim 5 is objected to for the absence of a space between "Claim" and "1".

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1 and 6, and claims 2-5, 7 and 8 dependent thereon, are indefinite in the recitation of "or an ortholog thereof" with regard to SEQ ID NO: 2. The specification at page 11 defines orthologs of HIO102 as genes from other species that retain the same function due to the presence of one or more protein motifs and/or 3-dimensional structure. And at page 8, the specification states that an ortholog of HIO102 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not

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limited to: signaling activity, binding activity, catalytic activity or cellular or extra-cellular localizing activity. However, the list of possible functional activities is open ended, and most of the activities listed are generic, such as catalytic activity, binding activity, and signaling activity, wherein these functional activities are found in many divergent polypeptides that are not associated with producing a high oil phenotype in a plant. The specification also discloses that the term “orthologs” infers evolutionary relatedness of sequences. However, determination of evolutionary relatedness of sequences is subjective. In addition, the specification does not set forth any protein motifs or 3-dimensional structure that would identify a sequence as an ortholog of HIO102. Thus, the use of “ortholog” in the claim does not set forth the metes and bounds of the claimed invention.

5. Claims 1 and 6, and claims 2-5, 7 and 8 dependent thereon, are indefinite in the recitation of “high oil phenotype relative to control plants” and “altered oil content phenotype relative to control plants”, given that it is unclear what is encompassed by “control plant” and what would be considered “high oil” or “altered oil”, and the specification fails to set forth the metes and bounds of this term.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to transgenic plants comprising a plant transformation vector comprising a sequence that encodes HIO102 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or an ortholog thereof, and wherein the plant has a high oil phenotype relative to control plants and methods of producing said transformed plant. However, the specification only provides a plant transformed with a nucleic acid encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 that when overexpressed produces a high oil phenotype in the plant. The specification does not identify any other sequences that produce a high oil phenotype, including any sequences that could be considered orthologs of HIO102.

8. The specification at page 11 defines orthologs of HIO102 as genes from other species that retain the same function due to the presence of one or more protein motifs and/or 3-dimensional structure. And at page 8, the specification states that an ortholog of HIO102 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not limited to: signaling activity, binding activity, catalytic activity or cellular or extra-cellular localizing activity. However, the specification does not describe any structural features of the polypeptides that confer any of the recited functional activities or that are required to confer the claimed function of producing a high oil phenotype in a transformed plant. Applicants are claiming a genus of sequences. However, only one sequence has been provided.

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“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaworski et al (US Patent 6,307,128).

11. The claims are drawn to a plant transformed with a nucleotide sequence that encodes or is complementary to a sequence that encodes the polypeptide of SEQ ID NO: 2 or an ortholog thereof, wherein the plant has a high oil phenotype relative to a non-transformed control plant. Claims are also drawn to a method of producing a high oil phenotype in a plant by transforming

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plant cells, growing the plants that have altered oil content, and plants obtained by said method.

It is noted that “high oil” is not defined, as set forth above.

12. Jaworski et al teach plants transformed with a nucleic acid (SEQ ID NO: 3, AR174887) encoding a sequence that is identical to the HIO102 polypeptide of SEQ ID NO: 2 or a sequence complementary thereto, wherein the plants are Brassica (rapeseed), sunflower, soybean or corn, for example (paragraphs 18-27 of the Description, for example), including methods of transformation, and a high oil phenotype or an altered oil content would be inherent in a plant comprising the same transgene. Jaworski et al also teach that said nucleic acid encodes a beta-ketoacyl synthase that is involved in the synthesis of long chain fatty acids in plants (paragraph 1 of the Description, for example).

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaworski et al (US Patent 6,307,128 in IDS of 7/31/06).

16. The claims are drawn to a plant transformed with a nucleotide sequence that encodes or is complementary to a sequence that encodes the polypeptide of SEQ ID NO: 2 or an ortholog thereof, wherein the plant has a high oil phenotype relative to a non-transformed control plant. It is noted that “high oil” is not defined, as set forth above. Claims are also drawn to a method of producing a high oil phenotype in a plant by transforming plant cells, growing the plants that have altered oil content, and plants obtained by said method. In addition, claim 5 is drawn to a method of growing the transgenic plant or claim 1 and recovering oil from said plant. It is noted that “high oil” is not defined, as set forth above.

17. Jaworski et al teach plants transformed with a nucleic acid (SEQ ID NO: 3, AR174887) encoding a sequence that is identical to the HIO102 polypeptide of SEQ ID NO: 2 or a sequence complementary thereto, wherein the plants are Brassica (rapeseed), sunflower, soybean or corn, for example (paragraphs 18-27 of the Description, for example), including methods of transformation, and a high oil phenotype or an altered oil content would be inherent in a plant comprising the same transgene. Jaworski et al also teach that said nucleic acid encodes a beta-ketoacyl synthase that is involved in the synthesis of long chain fatty acids in plants (paragraph 1 of the Description, for example). Jaworski et al further teach that methods of analyzing fatty acid composition were known at the time of the invention (see paragraph 24 of the Description).

18. Jaworski et al do not specifically teach recovering oil from said transgenic plants.



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19. Given the recognition of one of ordinary skill in the art of the value of transforming a plant with a nucleotide sequence encoding a polypeptide of SEQ ID NO: 2 or a sequence complementary thereto for the purpose of modifying the fatty acid content and/or composition of plant oils, which may be analyzed by known methods, as taught by Jaworski et al, it would have been obvious to one of ordinary skill in the art that recovering the oil from said transgenic plants is a required step prior to analysis of the fatty acids. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made to one of ordinary skill in the art, especially in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/  
Primary Examiner, Art Unit 1638